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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/657,019

09/05/2003

Shrirang Netke

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EXAMINER

CHOI, FRANK I

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

07/02/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/657,019	Applicant(s) NETKE ET AL.	
	Examiner FRANK I. CHOI	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,9-15 and 20-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,9-15 and 20-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 August 2007 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

The Amendment (6/26/2006) to the Specification is improper. The Amendment to the Specification must be done by replacement paragraphs, or sections or substitute specification. See 37 CFR 1.121 (b). The Applicant has not corrected the same, as such, the objection is maintained.

Drawings

The Examiner acknowledges the submission of replacement drawings (8/7/2007), however, the replacement drawings are still have informalities.

The drawings are objected to because Figs. 1-3 are unclear. The images of the bones are not sufficiently distinct from the background (the examiner suggests outline drawings or submission of photos provided that the photos are clear when photocopied). The background of Fig. 3 still obscures the data points. The background of the graph is too dark and obscures the data points. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet"

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pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 9-15, 20-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 202 07 569 U1 in view of Rosenberg et al. (US Pat. 6,579,544), Brown et al. (US Pat. 6,528,042), Fini et al., Ibsen et al., Dollwet et al. and Dodds et al..

DE 202 07 569 U1 discloses a dietary supplement containing lysine, proline, Vitamin C, copper, Vitamin B6 and Vitamins A, D3, B1, B2, niacin, folic acid, B12, biotin, pantothenic acid and calcium, phosphorous, magnesium, zinc, selenium, manganese, chromium, molybdenum, potassium, hesperidin, arginine, cysteine, myo-inositol, carnitine, ubiquinone and bioflavonoids (See entire document).

Rosenberg et al. discloses that vitamin C is essential for the healing of bone fractures and that such fracture heal slowly in a patient deficient in vitamin C (Column 9, lines 32-54). It is disclosed that bioflavonoids promote vitamin C activity and include hesperidin which is found in the rinds of oranges and lemons and proanthocyanidins (Column 18, lines 11-26). It is disclosed that Coenzyme Q10 (ubiquinone) is found in every cell in the body and serves to

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prevent the cellular damage the results from normal metabolic processes and that deficiencies can occur during stress (Column 21, lines 47-68).

Brown et al. disclose that the combination of flavonoids or flavonoids and synergists, where the flavonoid can be hesperedin or pycnogenol and the synergist can also be a flavonoid, carnitine, lysine, arginine or tocopherols and that pycnogenol and hesperedin are used for ameliorating injuries (Column 19, lines 20-68, Column 20, Column 21, lines 1-4).

Fini et al. disclose that the rationale for using lysine in fractures is that lysine stimulates intestinal calcium absorption and renal conservation and cross-linking process of bone collagen (page 214). It is disclosed that L-proline acts as a substrate for collagen synthesis (page 214).

Ibsen et al. disclose that administered proline is used during bone healing (Pages 803, 804).

Dollwet et al. disclose that copper supplementation increases the rate of bone healing (Abstract).

Dodds et al. disclose that delayed fracture healing was observed in vitamin B6 deficient rate (Abstract).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose a method for facilitating bone healing in a mammal by administering the combination of lysine, proline, ascorbic acid, copper and vitamin B6. However, the prior art amply suggests the same as the prior art discloses the same as a nutritional supplement, that vitamin C is necessary for healing bone fractures, lysine increases calcium in the body and stimulates cross-linking of collagen, proline is used as a substrate for collagen synthesis and in bone healing, that vitamin B6 deficiency leads to delayed fracture healing and that pycnogenol is suitable for use in compositions for ameliorating injuries. As such, one of ordinary skill in the

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art would have been motivated to administer the composition disclosed in DE 202 07 569 U1 wherein the flavonoids include pycnogenol with the expectation that the composition would be effective in increasing the rate of bone healing.

The Examiner has duly considered the Applicant's arguments but deems them unpersuasive.

The Supreme Court in *KSR International Co. v. Teleflex Inc.*, held the following:

(1) the obviousness analysis need not seek out precise teachings directed to the subject matter of the challenged claim and can take into account the inferences and creative steps that one of ordinary skill in the art would employ;

(2) the obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents;

(3) it is error to look only the problem the patentee was trying to solve-any need or problem known in the filed of endeavor at the time of invention and addressed by the prior art can provide a reason for combining the elements in the manner claimed;

(4) it is error to assume that one of ordinary skill in the art in attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem-common sense teaches that familiar items may have obvious uses beyond their primary purposes, and in many cases one of ordinary skill in the art will be able to fit the teachings of multiple patents together like pieces of a puzzle (one of ordinary skill in the art is not automaton);

(5) it is error to assume that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try". *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396, 1397 (U.S. 2007).

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The Applicant argues that none of the references discloses coenzyme Q10. However, DE 202 07 569 and Rosenberg disclose the use of coenzyme Q10, i.e. ubiquinone. Further, the prior art, as indicated above, does disclose the healing of bone. As such, one of ordinary skill in the art would have been motivated to use the prior art compositions to heal bone.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
Patent Examiner
Technology Center 1600
July 3, 2008

/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616